DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (201)
331-2909

December 12, 1996

WARNING LETTER

Mr. David A. Leighty, President
Perma Pure, Inc.
8 Executive Drive
Toms River, New Jersey 08754

Dear Mr. Leighty: File No: 97-NWJ-08

During an inspection of your firm located in Toms River, New Jersey, on September 24 - October 17, 1996, our Investigators determined that your firm manufactures accessory devices for medical gas analyzers. These products are medical gas dryers and are Class II devices, as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packaging, storage, or installation, are not in conformance with Good Manufacturing Practice (GMPs) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820, as follows:

1) Failure to conduct planned and periodic audits of the quality assurance program. Also, your firm lacks established written procedures to conduct such internal audits (FDA483 item 13).

2) Failure to demonstrate through adequate processing controls, testing and procedures that the device meets all established specifications, for example: water permeability has not been established for finished products (FDA483 item 1); incoming components are accepted without certificate of conformance and/or testing to confirm specifications (FDA483, item 2).

3) The Complaint Handling System is deficient, for example: complaints were found in which there was no documented evaluation by a responsible individual regarding the need for further investigation (FDA483, item 3); no documentation of testing of returned products to determine if the device failed to meet performance specifications (FDA483, item 4a); there was no documentation regarding the disposition of returned goods (FDA483, item 4b).

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4) Device Master Records are incomplete, for example: there are no specifications for the change in pressure range and/or engineering drawings (FDA483, item 6).

5) Review of Device History Records contained multiple examples of incomplete or inaccurate information, for example: results of finished product testing for change in pressure are not documented (FDA483, item 9); failure percentages for rejected lots were incorrect (FDA483, item 8); several records lacked documentation to indicate the disposition of rejected pieces and lacked accountability information regarding actual number of product produced, operator name and assembly dates (FDA483, item 12).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA and implement permanent corrective actions.

We are in receipt of your written response, dated November 6, 1996 regarding the FDA483 observations issued to your firm on October 17, 1996. While your proposed corrections appear to be acceptable, you did not include copies of revised procedures for our review. Revised procedures pertaining to complaint evaluations, internal audits and the evaluation of final product testing, need to be evaluated before we can determine the adequacy of your response. A follow-up inspection will be required, to assure that corrections effectively address the noted deficiencies.

Until it has been determined that corrections are adequate, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending submissions for premarket clearance for devices to which the GMP violation are reasonable related, will be cleared. As well, requests for Certificates for Products for Export, will not be approved. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, regarding the specific steps you have taken to correct the noted violations, including copies of the revised procedures referenced in your response. Also, indicate the anticipated date that your facility will be ready for reinspection to verify corrective actions taken.

Your response should be directed to the Food and Drug Administration, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mrs. Mercedes B. Mota, Compliance Officer.

Sincerely,

for MATTHEW H. LEWIS
District Director
New Jersey District

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

MBM:np